

Remarks

Claims 1, 3-7, 11-16, 24-28, and 31-35 were pending in the subject application. Favorable consideration of the claims, in view of the remarks set forth herein, is earnestly solicited.

Claims 1, 3-5, 11-16, 24, 25, 31, and 33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,385,631 (Uthmann). The applicant respectfully traverses because Uthmann does not teach or suggest several elements of the invention as currently claimed.

The subject invention is directed to a dual-lumen catheter having a co-axial configuration. In direct contrast, Uthmann is directed to a “double catheter,” wherein the catheters are placed in a side-by-side configuration. In fact, Uthman expressly teaches that the two catheters of his system are *not* co-axial in nature (see, for example, claims 1-13; col. 1, lines 40-42 and 58-62; and col. 2, lines 50-56). Uthmann states that his “two individual catheters are arranged longitudinally movable relative to each other, *by means of a longitudinal guide*” (col. 1, lines 40-42, emphasis added) such that the channels of the catheter run side by side and are *axially separated* (claim 1). Thus, Uthmann in no way teaches or suggests a dual catheter co-axial in configuration as claimed by the applicant.

The subject invention teaches a catheter in which the arterial lumen (blood removal) extends beyond the distal end of the venous lumen (return treated blood). With the Uthmann double catheter, the outlet opening of the *venous lumen* (the catheter that supplies return blood) is placed in the vein “in such a manner that the supply of blood takes place *so far ahead of the blood removal (arterial lumen)*... , that the blood returned into the vein does not move to the region of the blood removal location” (see col. 1, lines 45-53; and col. 4, lines 1-11; Figures 1, 5, and 8). Uthmann goes on to state that the placement of the catheters is very important (venous lumen is located a substantial distance ahead of the arterial lumen) because the occurrence of pendulum blood is avoided (see, for example, col. 1, lines 52-53; col. 4, lines 9-11).

Thus, the subject invention is the quintessential opposite of the Uthmann device. Unlike the device of Uthmann, which describes a dual, *side-by-side* configuration and a venous lumen that extends beyond the arterial lumen, the subject catheter is of co-axial configuration and the arterial lumen extends beyond the venous lumen when in use.

As the Patent Office is aware, all the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention. *In re Royka*, 490

F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). As discussed above, there is no teaching or suggestion in Uthmann to a co-axial dual lumen catheter whose arterial lumen extends beyond the distal end of the venous lumen. In fact, the Uthmann reference *teaches away* from the subject invention by suggesting that the placement of the venous lumen beyond the arterial lumen is necessary to avoid pendulum blood. In the absence of these important features, Uthmann would not produce the claimed invention and a valid *prima facie* case for obviousness of the claimed invention has not been established by the Patent Office. Therefore, the applicant respectfully requests reconsideration and withdrawal of the obviousness rejection under 35 U.S.C. §103 based on Uthmann.

Claims 27, 28, 32, 34, and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Uthmann in view of Zawacki (U.S. Patent No. 6,758,836). The applicant respectfully traverses. The Office Action asserts that Uthmann discloses the device of the subject invention except for the construction materials, hub, and placement methodology taught by Zawacki. The applicant respectfully disagrees. The arguments presented above that Uthmann does not teach the device of the subject claims are herein reasserted. Zawacki fails to cure or even address the deficiencies identified in the Uthmann reference. As noted in the Office Action, “Zawacki discloses a split tip dialysis catheter with slideable lumens.” This provides ***two distinct, separate, non-coaxially situated catheter tips*** necessarily extending in different directions and a device that comprises three different lumens as stated at col. 1, lines 63-67, and, as shown in the figures of the Zawacki reference. Thus, neither Uthmann nor Zawacki teach or suggest the claimed dual lumen catheter that is of co-axial configuration, wherein the arterial lumen extends beyond the venous lumen when in use.

With regard to the limitations presented in claims 27, 28, 32, 34, and 35 directed to the manufacturing materials, the placement methodology, and the use of reinforcing devices or a hub, the applicant respectfully asserts that these elements, as taught by Zawacki, do not cure the serious defects of both the Zawacki and Uthmann references discussed above. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection of claims 27, 28, 32, 34 and 35 under 35 U.S.C. §103(a).

Claim 26 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Uthmann in view of Davey *et al.* (U.S. Patent No. 6,595,966). The applicant respectfully traverses this rejection.

The Office Action contends that Uthmann discloses the device of the subject invention with exception of the use of a therapeutic agent.

The applicant disagrees that Uthmann discloses the device of the subject invention. As discussed in detail above, unlike the subject application, Uthmann discloses a double catheter of side-by-side configuration, where the venous catheter necessarily extends beyond the distal end of the arterial catheter. The use of the anticoagulant, heparin, taught by Davey *et al.* does not cure the defects of the Uthmann reference. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection of claim 26 under 35 U.S.C. §103(a).

In view of the foregoing remarks, the applicant believes that the pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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